The Medical Device User Fee and Modernization Act of 2002

— FAQs —

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The Medical Device User Fee and Modernization Act of 2002, amending the Federal Food, Drug, and Cosmetic Act, was signed by President Bush on October 26, 2002, and is now law.

Background

What is the Medical Device User Fee and Modernization Act of 2002?

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), P.L. 107-250, amends the Federal Food, Drug, and Cosmetic Act to provide FDA important new responsibilities, resources, and challenges. MDUFMA was signed into law October 26, 2002. MDUFMA has three particularly significant provisions:

- **User fees for premarket reviews**. Premarket applications (PMAs), product development protocols (PDPs), biologic license applications (BLAs), certain supplements, and 510(k)s are now subject to fees. The revenues from these fees, and from additional appropriations for infrastructure, will allow FDA to pursue a set of ambitious performance goals that will provide patients earlier access to safe and effective technology, and will provide more interactive and rapid review to the medical device industry. A small business (sales and receipts of $30 million or less) may pay a reduced fee. The payment of a premarket review fee is not related in any way to FDA's final decision on a submission.

- **Establishment inspections may be conducted by accredited persons (third-parties)**, under carefully prescribed conditions.

- **New regulatory requirements for reprocessed single-use devices,** including provisions requiring the submission of additional data on devices now being reprocessed, and a new category of premarket submission, the premarket report.

MDUFMA makes several other significant changes that are less complex or have a narrower scope than the major changes discussed above. FDA will provide additional information on these provisions in the near future:

- Additional appropriations for postmarket surveillance are authorized. The Act authorizes significant additional appropriations to strengthen FDA's postmarket surveillance of medical devices marketed in the United States. For FDA to actually receive these resources, Congress must pass appropriations acts authorizing these additional funds to FDA.

- The existing third-party 510(k) review program is continued through FY 2006.

- The review of combination products (products that combine elements of devices, drugs, or biologics) will be coordinated by a new office in the Office of the Commissioner.

- Electronic labeling is authorized for prescription devices intended to be used in health-care facilities.

- FDA may require electronic registration of device establishments, when feasible.

- The sunset provision applicable to section 513(i)(1)(E) (intended use based upon labeling) is revoked.

- The law now explicitly provides for modular review of PMAs.

- New provisions are added concerning devices intended for pediatric use.

- GAO and NIH are directed to prepare reports concerning breast implants.

- The manufacturer of a device must be identified on the device itself, with certain exceptions.

How do I obtain additional information on the requirements of the new law?

FDA has not yet completed its implementation plans for MDUFMA, and may not be able to answer all your questions at this time. We do have a variety of materials that will help you gain an understanding of the new law:

This web page at www.fda.gov/cber/mdufma/mdufma.htm as well as CDRH's web page at www.fda.gov/cdrh/mdufma will be updated and expanded periodically, and will provide the latest information and guidance from FDA concerning the new law.

- The full text of the new law is available in pdf (www.fda.gov/cdrh/mdufma/MDUFA 2002.pdf) and text (www.fda.gov/cdrh/mdufma/MDUFMA 2002.htm) formats.

- FDA has prepared a brief summary that provides additional information on the key provisions of the new law; this summary is available in pdf (www.fda.gov/cdrh/mdufma/MDUFMA Summary.pdf) and text (www.fda.gov/cdrh/mdufma/MDUFMA Summary.htm) formats.

- You can review the legislative history of MDUFMA on the Library of Congress *THOMAS* legislative information web site, (http://thomas.loc.gov). Search for these bills: H.R. 5651 (the bill that was enacted) and H.R. 3580 (a predecessor bill that led to H.R. 5651).

- CDRH's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) can answer basic questions concerning the new law, and help you find guidance documents and other reference materials. The agency is developing procedures for fee collection and qualification to be treated as a small business. When these procedures are completed, we will post them on the MDUFMA website.

- If you have a question that is not answered by DSMICA or the available reference materials, send an e-mail message to MDUFMA@cdrh.fda.gov. Questions on CBER-regulated devices may be submitted via e-mail to the following accounts: matt@cber.fda.gov (manufacturers) or octma@cber.fda.gov (consumers and health care providers).

Why has Congress authorized user fees?

MDUFMA recognizes that "the public health will be served" by providing additional funds to FDA for "the process for the review of devices and the assurance of device safety and effectiveness so that statutorily mandated deadlines may be met." FDA's medical device program resources have been reduced in recent years, and there have been indications that review performance has begun to decline. The user fees provided by MDUFMA, and the additional appropriations that go with the new law, will provide significant benefits:

- Safe and effective medical devices will reach patients more rapidly.
- Greater certainty that manufacturers will receive timely, high-quality reviews.
- Resources to ensure that devices marketed in the United States continue to meet high standards for safety and effectiveness.

What are the new fees?

For fiscal year 2003 (October 1, 2002 through September 30, 2003), the following fees will apply:

Table 1 — FY 2003 Device Review User Fees

Application	Standard Fee	Small Business
Premarket application (PMA, PDP, BLA)	$154,000	$58,520
Premarket report (premarket approval application for a reprocessed device)	$154,000	$58,520
Panel-track supplement	$154,000	$58,520
Efficacy supplement	$154,000	$58,520
180-day supplement	$33,100	$12,582
Real-time supplement	$11,088	$4,213
510(k)	$2,187	Not applicable during FY 2003*

*For FY 2003, all 510(k)s are subject to the standard fee of $2,187. The law provides for a reduced 510(k) fee for a small business in FY 2004 and later years.

FDA will adjust these fees each year to account for inflation, changes in workloads, and other factors. FDA will announce the new fees for the next fiscal year in a *Federal Register* notice by August 1 of each year.

FDA Questions and Answers on Medical Device User Fee Billing Issues

When will FDA begin Collecting Fees?

A fee must be paid for each premarket application, premarket report, supplement or 510(k) submitted on or after October 1, 2002, unless the applicant is eligible for a waiver or exception.

However, under the provisions of the new legislation, before FDA can begin collecting fees, Congress must also pass an appropriation act providing for the new medical device fees. FDA must develop systems to collect, safeguard, process, and account for fees. For these reasons:

Firms should not send a fee payment until FDA sends an invoice for applications submitted on or after October 1, 2002, or publishes a Federal Register notice providing detailed payment instructions.

Similarly, small business applicants who want to qualify for a reduced fee should not submit income tax forms or requests until FDA sends you an invoice for payment, or issues a detailed Federal Register notice providing payment instructions. The invoice or Federal Register notice will include instructions on where to send your payments and your request to be classified as a small business.

Will FDA consider electronic payments?

FDA will consider how to provide electronic fee payments. FDA's instructions will let firms know how electronic payments can be made.

How will FDA handle submissions made during this transition period between October 1, 2002 and the date FDA is able to begin accepting fees?

During this transition period, you should not send a fee payment with any submission. FDA is not canceling any submissions and is not asking applicants to withdraw any submissions due to lack of fee payment during this transition period. Review activities will continue as usual for all submissions made on or after October 1, 2002.

How will industry know what FDA is requiring?

After an enabling appropriation act has been passed by Congress, FDA will publish a more detailed Federal Register notice announcing a date firms should start sending user fee payments with submissions and instructions as to where to send the fee payments. FDA will also invoice those firms who submitted applications during this transition period between October 1 and the date FDA can start receiving payments. FDA will also publish the contents of this Federal Register notice with payment instructions on its web site.

Will there be fee waivers, exemptions, or reductions?

Fee waivers and exemptions. Under the new law, a fee will *not* be charged for certain submissions:

Table 2 — Fee Exemptions and Waivers (No Fee for These)

Category	Exemption or Waiver
HDE	Exempt from any fee.
BLA for a product licensed for further manufacturing use only	Exempt from any fee.
First premarket application (PMA, PDP, BLA, or premarket report) from a small business	One-time waiver of the fee that would otherwise apply.
Third-party 510(k)	Exempt from any FDA fee; however, the third-party may charge a fee for its review.
Any application for a device intended *solely* for pediatric use.	Exempt from any fee. If an applicant obtains an exemption under this provision, and later submits a supplement for adult use, that supplement is subject to the fee then in effect for an original premarket application.
Any application from a State or Federal Government entity.	Exempt from any fee *unless* the device is to be distributed commercially.

Reduced fees are available to protect small businesses. An applicant that qualifies as a small business is eligible for reduced fees. Small business fees are significantly less than the fees that would otherwise be assessed; see Table 1.

How can a small business qualify for reduced fees?

For fiscal year 2003, a small business is one with gross sales or receipts of no more than $30 million, including sales and receipts of all affiliates, partners, and parent firms; FDA may adjust this threshold in future years. An applicant who must pay a fee must pay the standard fee unless it qualifies as a small business. To qualify for reduced fees, a small business must submit Federal income tax forms (for itself, and all affiliates, partners, and parent firms), showing that its sales and receipts do not exceed $30 million. If the $30 million small business threshold is shown to reduce user fee revenues by more than 16%, FDA may adjust the threshold to a lower level.

You must qualify as a small business at least 60 days before your first submission in any fiscal year you want to pay the reduced small business fees.

Each year, as fees are adjusted, small business fees will be set at the following levels:

Determination of Small Business Fees	
Application	**Small Business Fee**
• Premarket application (PMA, PDP, BLA) • Premarket report (premarket approval application for a reprocessed device) • Panel-track supplement • Efficacy supplement • 180-day supplement • Real-time supplement	38% of standard fee
• 510(k)	80% of standard fee for FY 2004 and subsequent fiscal years

What can happen if I do not pay a fee that is due?

If a fee is not paid, the submission "shall be considered incomplete and shall not be accepted for filing" until the fee is paid in full. FDA will not begin its review of a submission until the fee for that submission is paid *and* all fees for *previous* submissions have been paid. If a fee is not paid within 30 days after it is due, the fee may be treated as a claim of the U.S. Government.

Under what circumstances will FDA refund part of a fee that has been paid for a premarket application, premarket report, or supplement?

If you make a written request within 180 days after the fee was due (see § 738(j)), FDA will refund 75% of a paid fee if we refuse to file a submission, or if the applicant withdrew a submission prior to our filing decision. § 738(a)(1)(D)(i) and (ii). If an applicant withdraws a premarket application, premarket report, or supplement *after* filing, but *before* a first action[1], FDA may, but is not required to, refund any portion of the fee, based on the level of effort already expended. FDA's decision to make or refuse a refund after filing, and our determination of the amount of any refund, is not reviewable. § 738(a)(1)(D)(iii). FDA will not refund any portion of a fee following a first action. If an applicant resubmits an application that FDA refused to file, or which the applicant withdrew, a new fee (full amount) must be paid.

How will FDA show that medical device review performance is improving?

The performance goals that FDA will pursue as part of the user fee program include specific year-by-year goals for improvement in device review times, as well as other important goals, such as maintaining performance in areas where specific goals have not been identified, using fee revenues for reviewer

[1] "First action" means major deficiency, not approvable, approvable, approvable pending GMP inspection, or denial.

training and expanded use of outside consultants and contractors, modular reviews, and improving the timeliness of premarket inspections. The law provides for annual reports by FDA and studies by GAO.

How soon will FDA show improvement in medical device reviews?

FDA's performance under the act is to be measured against goals set forth in the commitment letters from Secretary Thompson. These goals recognize that FDA needs to build infrastructure, hire and train new staff, and take other steps to lay the groundwork for success. The goals require significant, measurable improvements by FY 2005, but FDA will strive to show real improvement more quickly.

Sunset date.

FDA's authority to collect fees under MDUFMA expires October 1, 2007.

In addition, for fiscal years 2006 and 2007, if Congressional appropriations for the device program for that year do not meet certain levels, FDA may not assess medical device user fees for that year and FDA will not be required to meet performance goals for that year.

Third-Party Inspections

Why has Congress authorized third-party establishment inspections?

MDUFMA amends section 704 of the Federal Food, Drug, and Cosmetic Act to authorize FDA-accredited persons to inspect qualified manufacturers of class II and class III devices. These provisions are intended to help FDA focus its limited inspection resources on higher-risk inspections and give medical device firms that operate in global markets an opportunity to more efficiently schedule multiple inspections.

How much does an inspection cost, and who pays for it?

FDA does not set the fees that an accredited person may charge for an inspection, and FDA does not pay for such inspections. The establishment that wishes to use a particular third-party must negotiate the cost with the accredited person and is responsible for paying the negotiated fee.

Who can be accredited to conduct third-party inspections?

A person who wishes to be accredited by FDA to conduct establishment inspections:

- may not be an employee of the Federal Government;
- may not be owned by, or have an "affiliation (including a consultative affiliation)" with a device manufacturer, supplier, or vendor;
- cannot be engaged in the design, manufacture, promotion, or sale of FDA-regulated products;
- must operate "in accordance with generally accepted professional and ethical business practices" and must agree in writing to certain fundamental operating principles;
- may not have a financial conflict of interest regarding any FDA-regulated product.

Which establishments are eligible for inspection by a third-party?

To employ an accredited person in lieu of an FDA inspection, an establishment must meet certain conditions:

- the most recent inspection must have been classified as "no action indicated" or "voluntary action indicated."
- the establishment must notify FDA of the person it intends to use, and FDA must agree to the selection.
- the establishment must market a device in the United States *and* must market a device "in one or more foreign countries."
- the accredited person must be certified, accredited, or otherwise recognized by one of the countries in which the device is to be marketed.
- the establishment must submit a statement that one of the countries in which the device is to be marketed "recognizes an inspection of the establishment by [FDA]."

Are there effective controls to prevent possible conflicts of interest in the third-party inspection program?

MDUFMA includes very stringent provisions designed to avoid conflict of interests. As described above, an accredited person may not be owned by, or have an affiliation with a device manufacturer, supplier, or vendor; cannot serve as a consultant; cannot be engaged in the design, manufacture, promotion, or sale of FDA-regulated products; and cannot have a financial interest in any FDA-regulated product. The new law requires FDA to audit the performance of third-party inspectors and to review the compliance history of each establishment whenever it requests a third-party inspection. There are also severe penalties if an accredited person violates the law, including permanent debarment, civil money penalties, and criminal prosecution.

The law requires FDA to clear an establishment's choice of an accredited person whenever it wishes to obtain a third-party inspection. The law permits FDA to ask for additional information concerning the establishment's relationship with the third-party. And the law generally prohibits the use of third-parties for more than two consecutive inspections; this ensures that FDA will have the opportunity to continue to periodically inspect all establishments.

How soon will I be able to obtain a third-party inspection?

FDA must publish a *Federal Register* notice providing criteria for the accreditation of third-parties to conduct inspections by April 26, 2003. We intend to provide additional information in that notice. We expect the criteria we announce will be similar to, but not identical to, our criteria for third-party reviewers.

FDA must accredit third-parties by October 26, 2003; an eligible establishment would then be permitted to select any accredited person to conduct an inspection in lieu of an FDA inspection.

Sunset date.

The authority for third-party establishment inspections expires October 1, 2012.

How will reprocessed single-use devices be regulated under the new law?

Before enactment of the new law, the regulatory requirements for manufacturers of reprocessed single-use devices (the persons who are reprocessing the device) basically depended upon the class of the device. Manufacturers of reprocessed class I and II single-use devices were required to have a 510(k), unless the device was exempt from 510(k). Reprocessors of class III devices were required to obtain premarket approval. Under the new law, reprocessors of some exempt devices will no longer be exempt from the 510(k) submission requirements but rather will need to submit 510(k)s that include validation data. Validation data will also be required for many reprocessors of single-use devices that are currently the subject of cleared 510(k)s. Finally, reprocessors of class III devices will need to submit a premarket report (a new type of premarket application). More detail is provided below.

If my reprocessed single-use device was 510(k) exempt before the new law, is it still exempt?

Not necessarily. By April 26, 2003, FDA will review the types of *critical* reprocessed single-use devices[2] that are currently *exempt* from 510(k), and determine which of these exemptions will be terminated. FDA must publish a Federal Register notice listing these devices. 510(k)s submitted for these devices must include validation data (as described below), and must be submitted within 15 months of publication of the list.

By April 26, 2004, FDA is to review the types of *semi-critical* reprocessed single-use devices[3] that are currently exempt from 510(k), and determine which of these exemptions will be terminated. FDA must publish a Federal Register notice listing these devices. 510(k)s submitted for these devices must include validation data, and must be submitted within 15 months of publication of the list.

Reprocessed single-use devices not included on either the critical or semi-critical device lists may continue to be marketed without submission of a 510(k).

When will FDA require validation data for reprocessed single-use devices that already require 510(k) clearance (i.e., devices that are not 510(k) exempt)?

By April 26, 2003, FDA will review the types of reprocessed single-use devices now subject to 510(k) clearance and identify those that FDA will now require to submit "validation data . . . regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent . . . after the maximum number of times the device is reprocessed as intended" by the person who submits the 510(k). FDA must publish a list of these devices in the Federal Register and update the list when necessary. A 510(k) for one these devices, submitted after publication of the

[2] A "critical reprocessed single-use device" is a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use. …

[3] A "semi-critical reprocessed single-use device" is reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

list, must include validation data. Validation data must also be submitted for a device that already has a cleared 510(k), or marketing must cease; the validation data must be submitted within nine months of the date FDA includes the device on the list of devices for which validation data is required.

When will FDA require premarket reports for class II reprocessed single-use devices?

The requirement for submission of premarket reports for class III reprocessed single-use devices went into effect on the act's effective date, October 26, 2002. Previously, PMAs were required for these devices.

What labeling changes are required for reprocessed single-use devices and when must the new labeling be used?

Any reprocessed single-use device (i.e., devices exempt from 510(k) requirements, subject to 510(k) requirements, or subject to a premarket report) introduced into interstate commerce after January 25, 2004 must "prominently and conspicuously" bear the statement:

> Reprocessed device for single use. Reprocessed by [name of manufacturer that reprocessed the device].

This provision will make it easier for patients and health care professionals to know when they are using a reprocessed device.

Postmarket Surveillance

Does the new law do anything to strengthen postmarket surveillance?

MDUFMA authorizes additional appropriations for postmarket surveillance — $3 million for FY 2003, $6 million for FY 2004, and "such sums as may be necessary" in subsequent years. An authorization for additional appropriations does itself not provide FDA any additional resources. For FDA to receive these resources, Congress must pass appropriations acts providing these additional funds to the agency.

In addition, MDUFMA requires FDA to conduct, and submit to Congress by January 10, 2007, a study of:

- the effect of medical device user fees on FDA's ability to conduct postmarket surveillance.
- the extent to which device companies comply with postmarket surveillance requirements.
- any improvements needed for adequate postmarket surveillance, and the amount of funds needed to do so.
- recommendations as to whether, and in what amount, user fees should be used for postmarket surveillance, if extended beyond FY 2007.